REMARKS

AMENDMENTS

Applicants have canceled Claim 84; and added Claim 87. Thus, Claims 52, 54-55, 83, and 85-87 are currently pending.

Applicants have adopted the Examiner's suggestions and amended the claims to place the claims in proper dependent form by adding Claim 87 and canceling Claim 84.

None of these amendments adds new subject matter and their entry is respectfully requested.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

ELECTION/RESTRICTIONS

Applicants affirm the election without traverse of Group II, Claims 49 and 52-84, and an election of species of compound IA-6 from page 55 of the specification.

STATUS OF THE CLAIMS

The Examiner has grouped Claims 85-86 in Group II of the restriction requirement made on December 9, 2005. Applicants affirm that Claims 52, 54-55, and 83-86 are pending in the instant application.

PREVIOUS CLAIM OBJECTIONS AND REJECTIONS

Applicants acknowledge with appreciation that the Examiner has withdrawn previous objections to Claims 49, 52-55, and 83-86, previous objection to Claim 83, previous 35 U.S.C. § 112 rejections of Claims 49 and 84, previous 35 U.S.C. § 102 rejections of Claims 49, 55, and 84, and previous 35 U.S.C. § 103 rejections of Claims 49 and 53.

NEW CLAIM OBJECTIONS

The Examiner has objected to Claim 84, 85, and 86 under 37 CFR 1.75(c) as being in improper dependent form and suggested that Applicants cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As noted above, Applicants have adopted the Examiner's suggestion and amended the Claims. Accordingly, Applicants respectfully request that the Examiner withdraw this objection.

CLAIMS REJECTIONS – 35 U.S.C. § 103

The Examiner has maintained the rejection of Claims 52, 54-55, and 83-84 as allegedly being obvious over Kästner et al. (DE 41 26 543 A1, hereinafter "Kästner"). In responding to Applicants' reply, the Examiner states that "[t]he requirements for a *prima facie* case of obviousness are provided by teaching the limitations of the claims by the combined teachings of the prior art, providing a motivation to the person of ordinary skill to combined the teachings, and to provide the person of ordinary skill in the art a reasonable expectation of success." The Examiner bases the rejection on the statement that "[t]he motivation to synthesize a compound in the prior art can be different from the motivation of Applicant to synthesize the claimed compounds as a product is being claimed and not a method of use". The Examiner has further rejected Claims 85-86 under 35 U.S.C. § 103 over Kästner. Applicants traverse.

Applicants respectfully disagree with the Examiner and submit that the claimed invention must be considered as a whole and, specifically, the non-obviousness of compounds as a product must be determined by taking into consideration of their biological or pharmacological properties.

The following is a quotation of MPEP § 2141.02 which delineates the difference between prior art and claimed invention:

> Ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole.
>
> .....

V. DISCLOSED INHERENT PROPERTIES ARE PART OF "AS A WHOLE" INQUIRY

"In determining whether the invention as a whole would have been obvious under 35 U.S.C. 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter and are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention as a whole, and not some part of it, which must be obvious under 35 U.S.C. 103." *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977) (emphasis in original)

Furthermore, *In re Papesch* established that courts have historically "determined the unobviousness and patentability of new chemical compounds by taking into consideration their biological or pharmacological properties." *In re Papesch*, 315 F.2d 381, 391, 137 U.S.P.Q. 43, 51 (C.C.P.A. 1963). "Patentability has not been determined on the basis of the obviousness of structure alone." *Id.* "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." *Id.* "And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison." *Id.*

Applicants respectfully submit that this invention, taken as a whole, is non-obvious over Kästner. Although drawn to a product, not a method of use of a product, claims of this application must be considered in light of compounds and their inseparable biological or pharmacological properties. When viewed on the whole, taking into account their pharmacological properties, the compounds of the instant invention are indeed different and non-obvious over Kästner. Applicants claim pyrazole derivatives as a product to treat ABC transporter mediated diseases. Kästner, on the other hand, teaches compounds of the formula

as dual inhibitors of Lipoxygenase and Cyclooxygenase. The mere fact that references can be combined or modified does not render the resultant combination obvious

unless the art also suggests the desirability of the combination. *See In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Notably, Kästner does not suggest either explicitly or implicitly the use of applicants' pyrazole derivatives to treat ABC transporter mediated diseases, thereby failing to provide a motivation or a reasonable expectation of success to the person of ordinary skill to synthesize compounds of this invention and apply their pharmacological properties towards ABC transporters.

Applicants respectfully submit that the instant invention is non-obvious over Kästner and, accordingly, Applicants request that the Examiner withdraw the rejection of claims 52, 54-55, and 83-86 under 35 U.S.C. § 103(a).

CONCLUSION

Applicants respectfully request that the Examiner enter the above amendments, consider the accompanying remarks, and allow the claims to pass to issue. Should the Examiner deem a telephone discussion expeditious to further the prosecution of the present application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

/Nancy K. Brennan/
Nancy K. Brennan, Ph.D. (Reg. No. 58,990)
Agent for Applicants
Nandakumar Govindaswamy, Ph.D. (Reg. No. 56,285)
Attorney for Applicants
c/o Vertex Pharmaceuticals Incorporated
130 Waverly Street
Cambridge, MA 02139-4242
Tel.: (617) 444-6790
Fax.: (617) 444-6483